

**REMARKS**

Applicants' request that the maintenance of rejection set out in the Advisory Action be reconsidered in view of the following remarks.

**The rejection under 35 USC §102(e)**

The examiner maintained the rejection claims 25 through 54 under 35 USC §102(e) for assertedly being directed to subject matter anticipated by the disclosure of Altman. Specifically, the examiner was of the opinion that the previous amendment to the claims to recite that the claimed method requires implant to be dehydrated "in its entirety" does not in fact recite that the "entire implant" is subject to this treatment and that "[b]y dehydrating a portion of his implant, Altman meets the requirement of having a dehydrated implant." [previous Action at page 3]. The applicants respectfully disagree with the examiner's construction of the claim as previously amended, and further note that dehydration of an implant in its entirety is fully supported by the specification.

First, claim 25 specifically defines production of an implant by providing a pair of bone anchors joined by a filament wherein the combination of bone anchors a filament are then incubated specification in a solution to form a matrix layer. The implant thus produced, by the express language of the claim, includes all of these components, so when the claim then requires the "implant" to be dehydrated, it is the complete product, and not a portion thereof that is treated in this manner. Inasmuch as the applicants have previously amended the claim to recite the implant "in its entirety" as suggested by the examiner, it is noted that this amendment simply makes explicitly clear what the claim itself recited prior to amendment.

Second, the subject matter of the claim, before and after the previous amendment, is fully supported by the specification.

Previously, the applicants pointed out that in the specification as originally filed in parent application USSN 09/990,320, claim 27 recites dehydration of an implant prepared by the method of claim 25. The two claims are reproduced below.

25. A method of preparing an implant for connective tissue substitution in an animal, said method comprising the steps of: a) providing a set of bone anchors by joining a pair of bone plugs at their proximal ends by at least one support filament; and b) incubating at least one time said set of bone anchors of step a) in a solution containing matrix forming molecules for a period time sufficient for the formation of at least one matrix layer around said support filament, wherein said matrix layer has a thickness sufficient to allow for colonization by cells, and wherein said incubation is performed under conditions in which are induced waves, vibrations, cyclic tractions, and/or static tractions of said implant.
27. The method according to claim 25, wherein said implant is dehydrated, lyophilized and/or chemically treated prior to implantation.

Claim 25 thus describes a method to produce an implant wherein bone anchors formed with bone plugs joined by a support filament, the entirety of which is incubated in a solution of matrix-forming molecules that forms a matrix layer around the support filament. With the entire implant thus formed, claim 27 requires the implant to be dehydrated, lyophilized and/or chemically treated prior to implantation. This step necessarily requires some type of treatment on the whole implant (i.e., the implant in its entirety), and not on individual components of the implant. The process step recited in original claim 27 is consistent with disclosure in the specification.

For example, paragraphs 96 through 100 in the specification as originally filed describe production of bioengineered ligament substitutes (i.e., implants). In paragraphs 96 and 97, bone anchors are provided wherein holes are made in each and the anchors are connected with surgical thread. Paragraphs 98 and 99 describes alternative collagen solutions in which the thus formed implant is then incubated. Paragraph 100 then describes incubation of the two bone anchors linked by the surgical thread (i.e., the implant) in the collagen solution such that collagen scaffolds are cast between the two anchors. At this point, preparation of the implant in its entirety as recited in original claim 25 is complete, and paragraph 100 then states that this tissue construct (i.e., the entire implant) is put into a desiccator and is completely dehydrated within about two to three hours.

Similarly, paragraphs 105 through 109 in the specification as originally filed describes preparation of periodontal ligament substitutes (i.e., implants) wherein teeth pieces are provided, hole are drilled in each, and the pieces are then connected with surgical thread

as specifically described in paragraphs 105 and 106. As above, alternative collagen solutions are described in paragraphs 107 and 108, and the incubation process is described in paragraph 109 wherein a collagen scaffold is cast between the tooth anchors joined by the surgical thread. After this incubation step, the complete tissue construct (i.e., the implant in its entirety) is desiccated. While paragraph 109 goes on to describe how another layer of collagen *can* be added after desiccation, this extra step is simply an alternative embodiment that need not be carried out.

In each of these disclosures, the implant in its entirety is defined as having two anchors connected by a filament and including a collagen casting. It is explicitly disclosed that this entire implant is dehydrated, and not simply individual components. Accordingly, the applicants submit that the specification fully supports the subject matter of claim 1 as previously amended and the rejection for assertedly lack of written description must be withdrawn.

### **CONCLUSION**

In view of the remarks herein, the applicants believe that all claims are now in condition for allowance and respectfully request notification of the same.

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Respectfully submitted,

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